ACCESS OPENINGS IN VACUUM BANDAGE

BACKGROUND OF THE INVENTION

The present disclosure relates to bandages for wounds, and more particularly to bandages for use with a vacuum and/or irrigation source.

The prior art contemplates that chronic wounds may be treated by providing a vacuum in the space above the wound to promote healing. A number of prior art references teach the value of the vacuum bandage or the provision of vacuum in the space above the surface of a chronic wound.

A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. Applying vacuum to the wound surface promotes healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound and for creating vacuum under the cover. If the cover is a flexible cover, which is typically more comfortable for the patient, a porous packing may be provided under the cover to fill the space in which the vacuum is formed. It will be appreciated, however, that the packing will be omitted by many caregivers, and it may be preferable not to have packing. The following U.S. Patents establish the nature of vacuum treatment bandages and devices: 6,095,992, 6,080,189, 6,071,304, 5,645,081, 5,636,643, 5,358,494, 5,298,015, 4,969,880, 4,655,754, 4,569,674, 4,382,441, and 4,112,947. All of such references are incorporated herein by reference for purposes of disclosing the nature of such vacuum treatment of wounds.

As shown, for example, in U.S. Patent No. 5,645,081 (hereinafter the '081 patent), a method of treating tissue damage is provided by applying negative pressure to a wound. The negative pressure is provided in sufficient duration and magnitude to promote tissue migration in order to facilitate the closure of the wound. Fig. 1 of the '081 patent discloses an open cell polyester foam section covering the wound, a flexible hollow tube inserted into the foam section at one end and attached to a vacuum pump at another end, an adhesive sheet overlying the foam section, and tubing to adhere to the skin surrounding the wound in order to form a seal that allows the creation of a vacuum when the suction pump is operating. The '081 patent further teaches use of negative pressure between about 0.1 and 0.99 atmospheres and that the pressure can be substantially continuous and is relieved only to change the dressing

on the wound. Alternatively, the '081 patent teaches use of a cyclic application of pressure in alternating periods of application and non-application. In a preferred embodiment, pressure is applied in five- minute periods of application and non-application.

Various other prior art references teach the value of the vacuum bandage or the provision of vacuum to the surface of a chronic wound. Several Russian language articles exist which establish the efficacy of vacuum therapy in the 1980's. Examples of such prior art articles, each of which discusses the use of application of vacuum to a wound to promote healing, are as follows: "Vacuum therapy in the treatment of acute suppurative diseases of soft tissues and suppurative wounds", Davydov, et al., Vestn, Khir., Sept. 1988 (The Sept. 1988 article); "Pathenogenic mechanism of the effect of vacuum therapy on the course of the wound process", Davydov, et al. Khirurigiia, June 1990 (the June 1990 article); and "Vacuum therapy in the treatment of suppurative lactation mastitis", Davydov, et al. Vestn. Khir., Nov. 1986 (the Nov. 1986 article).

The Russian articles distinguish wound drainage from use of vacuum therapy for healing. The Russian authors report that vacuum therapy resulted in faster cleansing of the wound and more rapid detoxification than with the traditional incision-drainage method. The November 1986 Russian article describes the vacuum therapy techniques as a reduction of 0.8-1 atmosphere for 20 minutes at the time of surgery, and subsequent 1.5 to 3 hour treatments at a reduced pressure of 0.1 to 0.15 from atmosphere, twice daily. These Russian articles teach the use of negative pressure to effect healing. The articles describe using several sessions per day, each lasting up to one hour, with a vacuum of 76-114 mmHg. The Russian articles teach using this vacuum method to decrease the number of microbes in the wound. The June 1990 Russian article teaches that this vacuum therapy provides a significant antibacterial effect. The article describes the stepped up inflow of blood to the zone around the wound to lead to an increase in the number of leukocytes reaching the focus of inflammation. Subsequent articles and patents further develop the benefits obtained with vacuum therapy.

SUMMARY OF THE INVENTION

The present invention comprises one or more of the following features, discussed below, or combinations thereof:

A member for use with a wound having a wound surface is provided. The member is also provided for use in a vacuum bandage connected to a vacuum source. The member may include a top surface and a bottom surface adapted to be in contact with and generally conform to the wound surface. The member may further include a plurality of discrete holes formed in the bottom surface and at least one discrete opening formed in the top surface. The member may include a port communicating with the vacuum source, each discrete hole, and at least one discrete opening.

The member may be formed from a generally non-porous material. The member may include a wound contacting layer having channels formed therein and a cover coupled to the wound contacting layer to cooperate with the channels of the wound contacting layer to define a set of passageways.

The cover may have a first surface area and the wound contacting layer may have a second surface area that is larger than the first surface area. The channels of the wound contacting layer may extend beyond an outer edge of the cover to define the plurality of discrete openings in an outer peripheral portion of the member.

The cover may include a plurality of discrete holes in communication with the channels of the wound contacting layer to define the plurality of discrete openings of the member.

Features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of the preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived.

BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description particularly refers to the accompanying figures in which:

Fig. 1 is a part perspective and part diagrammatic view of a wound care bandage showing the wound care bandage located on the leg of a patient and

coupled to both a vacuum source and an irrigation source through the use of a switch valve;

Fig. 2 is an exploded perspective view of the wound care bandage positioned above a wound bed showing a wound contacting layer and a cover of the bandage which cooperate to form a wound dressing member for placement within the wound bed, and showing the member having a top surface with peripheral openings that communicate negative pressure to tissue that overhangs areas of undermining in the wound;

Fig. 3 is a top plan view of the member of the bandage showing the cover of the member being smaller than the wound contacting layer of the member in order to expose peripheral openings of the member;

Fig. 4 is a perspective view of a portion of the member of the bandage showing the peripheral openings of the member; and

Fig. 5 is a sectional view of the bandage over the wound showing tissue overhanging the peripheral openings in communication with undermined portions of the wound in order to provide suction and irrigation to the areas of undermining.

DETAILED DESCRIPTION OF THE DRAWINGS

A vacuum bandage 10 is provided for use with a wound 12 having a wound surface 13, shown in Fig. 2. Vacuum bandage 10 includes a thin, flexible wound dressing member 19 having upper peripheral access openings (including access channels 62 and access holes 64) to allow member 19 to communicate with the wound surface 13 of wound 12 and with undermined portions 15 of wound 12. Member 19 includes a wound contacting layer 20 and a cover 22 coupled to the layer 20. Cover 22 is smaller than layer 20 to create access channels 62, as shown in Fig. 4. Member 19 also includes a connector 23 coupled to cover 22 for communication with vacuum source 14 and/or irrigation source 16. Bandage 10 further includes a sealing layer film, or outer cover 50 to be placed over member 19 and wound 12 to seal about the wound 12 to a patient's healthy skin 52 to create a sealed environment between wound surface 13 and outer cover 50.

Vacuum bandage 10 is provided for use with a vacuum source 14 and an irrigation source 16 through the use of a switch valve 55, as shown in Fig. 1.

Bandage 10 promotes the healing of wound 12, including undermined portions 15 of wound 12, by providing vacuum therapy to the wound 12 and undermined portions 15 of the wound 12 to promote blood flow and remove exudate from wound surface 13 and by providing for irrigation of the wound 12 with fluids such as saline, for example. An illustrative wound treatment apparatus having a wound temperature control system, a medicine delivery system, and a drainage system is disclosed in U.S. Patent No. 6,458,109. An illustrative vacuum and irrigation system is disclosed in U.S. Patent Publication No. US 2002/0161317 A1. Additionally, an illustrative vacuum bandage is disclosed in U.S. Patent Publication No. US 2002/0065494 A1. Alternative vacuum bandages are disclosed in U.S. Patent Publication No. US 2002/0082567 A1 All of these applications are hereby incorporated herein by reference.

As stated above, access openings 62, 64 are provided to allow vacuum suction and irrigation to be dispensed on the top as well as the bottom of member 19, as is described in more detail below. As shown in Fig. 4, access openings include both access channels 62 and access holes 64. It is also within the scope of this disclosure for member 19 to include either access channels 62 or access holes 64 formed in a top surface of member 19. Access openings 62, 64 are especially beneficial for undermined wounds. Undermined wounds are wounds in which the a portion of the sides or side walls of the wound have been eroded away such that a portion of tissue 17 is left overhanging the area 15 that has eroded.

Referring now to Fig. 2, member 19, layer 20, cover 22, and connecter 23 are each made of a medical grade silicone or other type of pliable elastomer. Two companies, for example, which manufacture such medical grade silicone are GE Silicones and NuSil Technology. It is within the scope of this disclosure, however, to include a member made of any type of thin, flexible material that is non-porous and non-foam-like. This thin, flexible material is also generally non-absorptive. For example, materials such as polyvinylchloride (PVC), PVC free of diethylhexyl phthalate (DEHP-free PVC), polyurethane, or polyethylene may be used in the manufacture of member 19. Further, layer 20, cover 22, and connecter 23 may each be molded to include anti-microbial constituents. For example, it is within the scope of this disclosure to impregnate member 19 with silver ions which are known anti-microbials.

Member 19, including layer 20, cover 22, and connecter 23, is also made of a generally non-adhesive material. Therefore, wound contacting layer 20, which lies adjacent to the wound surface 13, does not adhere to the wound surface 13. Further, member 19 is solid in nature and generally non-compressible. Member 19 is also transparent, as shown in Fig. 3. Therefore, a caregiver or user is able to see the wound 12 through member 19 when member 19 is placed adjacent to wound surface 13. This transparency allows the caregiver to view the progress of the healing of the wound 12.

Layer 20 includes or wound contacting surface 24 and an upper or opposite surface 26. Wound contacting surface 24, or portions thereof, contact and generally conform to the wound surface 13. Opposite surface 26 includes a central area 28 and a plurality of channels 30 spaced-apart from and extending radially away from central area 28. Central area 28 is recessed relative to the portions of upper surface 26 between channels 30. As shown in Figs. 3 and 4, channels 30 are open at the sides and ends of member 19. As is described below, channels 30 form access channels 62 at the periphery of member 19. Opposite surface 26 further includes concentric channels 31. Illustratively, each channel 30 is 0.030 inch (0.762 mm) wide and 0.030 inch (0.762 mm) deep. It is within the scope of this disclosure, however, to include channels 30, 31 of opposite surface 26 having various widths and depths suitable for the present application. Central area 28 of layer 20 is provided to communicate with the vacuum source 14 and irrigation source 16 through a port 40 of cover 22, as will be described below.

A plurality of radially extending protrusions or bosses 32 are positioned around central area 28. Bosses 32 are positioned between central area 28 and channels 30, 31, as shown in Fig. 1. Bosses 32 are provided to prevent central area 28 from collapsing in on port 40 of cover 22 to form a seal and effectively block air flow through port 40 while suction is applied to the bandage 10. Port 40 communicates with the vacuum source 14 and/or the irrigation source 16 via connecter 23 and tube 41, as shown in Figs. 1 and 2. As shown in Fig. 5, tube 41 is coupled directly to connecter 23. Tube 41 may also be coupled to connecter 23 by a barbed tube coupler (not shown).

As mentioned above, port 40 is in communication with central area 28 of layer 20. Illustratively, four bosses 32 are shown in Fig. 1. However, it is within

the scope of this disclosure to provide any number of bosses 23 or the like around central area 28 of layer 20 to prevent central area 28 from sealing off port 40 of cover 22 as suction is applied to bandage 10. Further, it is within the scope of this disclosure to include a boss or bosses having any shape in order to prevent central area 28 from sealing off port 40 when vacuum source 14 is running.

Connecter 23, as shown in Figs. 1 and 2 is a tubal port coupled to a top surface 36 of cover 22 and in communication with port 40 of cover 22. As mentioned before, it is within the scope of this disclosure for connector 23 to be a separate component of member 19 which is coupled to cover 22 or for connecter 23 to be coupled to cover 22 by being molded integrally with cover 22. Connector 23 includes a passageway formed at a right-angle. Thus, the passageway in connecter 23 has a vertical portion 25 that communicates with port 40 and a horizontal portion 27 that communicates with vertical portion 25. Connector 23 may also be molded to include a single passageway positioned at an angle with respect to cover 22. Connector 23 connects with tube 41 to provide a horizontal tube attachment for tube 41. Cover 22 includes a bottom surface 34 and top surface 36, as shown in Fig. 1. Bottom surface 34 engages opposite surface 26 of layer 20, as shown in Fig. 2.

In some embodiments, member 19 is formed by heat sealing opposite surface 26 of layer 20 and bottom surface 34 of cover 22 together and by heat sealing connecter 23 to top surface 36 of cover 22. For example, each of connecter 23, cover 22 (or the combination of cover 22 and connecter 23), and layer 20 may be pre-shaped and formed from semi-cured silicone. Once the connecter 23, cover 22, and layer 20 are placed together appropriately, the entire member 19 may be heated to heat seal and cure each of the three components to one another. Alternatively, for example, the cover 22 only may be made from semi-cured silicone while the connecter 23 and layer 20 may be made from fully cured silicone. Once placed together and heated, connecter 23 and layer 20 will heat seal to cover 22. Semi-cured silicone may be bought and pre-molded from a manufacturer such as NuSil Technology, for example.

Although the method of heat sealing the cover 22, connecter, and layer 20 to each other is disclosed, it is within the scope of this disclosure to form member 19 by coupling layer 20, cover 22, and connector 23 together by any other suitable means such as through the use of adhesives, for example. Further, it is within the

scope of this disclosure to provide a member 19 where cover 22 lies adjacent to, but is not coupled to, layer 20.

As mentioned above, cover 22 is coupled to layer 20 and connecter 23 is coupled to cover 22 to form member 19. Cover 22 and layer 20 cooperate to form discrete passageways 42 of member 19 defined by channels 30, 31 of layer 20 and bottom surface 34 of cover 22, as shown in Fig. 5. Passageways 42 extend from an outer edge 66 of cover 22 and are in communication with central area 28 of layer 20. Illustratively, cover 22 has a first surface area and layer 20 has a second surface area larger than the first surface area. Therefore, outer portions of radial channels 30 extend between outer edge 66 of cover 22 and outer edge 68 of layer 20 to define peripheral access channels 62 for providing vacuum suction or irrigation to undermined portions 15 of wound 12. Central area 28 of layer 20 is in communication with port 40 of cover 22 which is in communication with the vacuum and/or irrigation sources 14, 16, via connecter 23, and tube 41. Therefore, peripheral access channels 62 are in communication with the vacuum and/or irrigation sources 14, 16 via passageways 42.

Layer 20 includes through holes 46 which extend from channels 30, 31 to wound contacting surface 24, as shown best in Fig. 5. Holes 46 are discrete and are provided to communicate with channels 30, 31 of layer 20. Holes 46 therefore communicate with passageways 42 of member 19 and the vacuum and/or irrigation sources 14, 16 as well to allow the suction from the vacuum source 14 and/or the fluid from the irrigation source 16 to reach the wound bed surface 13 via the holes 46. Illustratively, holes 46 are 0.020 inch (0.508 mm) in diameter and are spaced approximately 0.500 inch (12.700 mm) apart along channels 30, 31 of layer 20. It is, however, within the scope of the disclosure to include holes having other suitable sized diameters and/or other suitable spacing that allow for the removal of exudate without generally clogging.

As mentioned above, member 19 further includes peripheral access holes 64. Specifically, holes 64 are formed through cover 22 and are positioned near outer edge 66, as shown in Fig. 4. Holes 64 are in communication with passageways 42 to provide either suction or irrigation to undermined portions 15 of wound 12. Although member 19 is shown to include both peripheral access channels 62 and peripheral access holes 64, it is within the scope of this disclosure to include a

member having either peripheral access channels 62 or peripheral access holes 64. Further, it is within the scope of this disclosure to include a member having other suitable access openings in addition to or in replacement of channels 62 and holes 64. As shown in Fig. 5, undermined portions 15 of wound 12 are in communication with peripheral access openings 62, 64 to directly expose undermined portions 15 to suction and irrigation treatment. Furthermore, member 19 can be manufactured to have sizes (i.e., thickness, length, width, etc.) and/or shapes (rectangular, square, triangular, round, etc.) other than those shown for use in wounds of various sizes and shapes. The member 19 may be cut to fit wound 12 to lie at the bottom of wound 12 adjacent wound surface 13.

It is within the scope of this disclosure to include an adhering, but removable, piece of disposable paper on the top surface of member 19 so that a caregiver may trace the shape of the wound 12 onto the paper and cut the member 19 to fit wound 12. Further, member 19 may be trimmed to leave a space of 1/4 inch (6.35 mm) to 1/2 inch (12.7 mm) or greater between the cut outer edge of member 19 and an inner boundary edge of wound 12. It is not necessary for member 19 to be in contact with the entire wound surface 13. As shown in Fig. 5, member 19 is sized to fit under overhanging tissue 17 into undermined areas 15 of wound 12. Member 19 may also be trimmed so that certain portions of member 19 are sized to fit into irregular undermined areas 15 of a wound.

Member 19, including layer 20, cover 22, and connecter 23, includes a top surface and a bottom surface. The bottom surface of member 19 is wound contacting surface 24 of layer 20. The top surface of member 19, however, includes top surface 36 of cover 22 and the portion of upper or opposite surface 26 of layer 20 positioned between outer edge 66 of cover 22 and outer edge 68 of layer 20. Therefore, the access openings (including access channels 62 of layer 20 and access holes 64 of cover 22) are formed in the top surface of member 19.

As mentioned above, bandage 10 further includes a sealing layer or film 50 that is placed over cover 22 and around tube 41, as shown in Fig. 2. Film 50 acts as an outer cover of the bandage 10 and covers the entire wound 12 by extending over wound 12 and attaching to the patient's healthy skin 52, also as shown in Fig. 2. Preferably, film 50 is an occlusive or semi-occlusive material which allows water vapor to permeate through. Because of this characteristic, the film 50 is referred to as

Moisture Vapor Transmission Rate film or MVTR film. The products TEGADERM® brand sealing film made by 3M Corporation, and OPSITE FLEXIGRID® semi-permeable dressing made by Smith & Nephew can be used for film 50, for example. Film 50 is approximately 0.003 inch (0.076 mm) thick. However, it is within the scope of this disclosure to include any occlusive or semi-occlusive film 50 having another thickness. Film 50 is provided to create a sealed environment below the film 50 and around the wound 12 in which a vacuum or negative pressure can be maintained as provided by vacuum source 14. Film 50 therefore creates a vacuum space 53 below film 50 and above wound surface 13.

As shown in Fig. 2, sealing film 50 is positioned adjacent top surface 36 of cover 22. It is within the scope of this disclosure, however, for bandage 10 to further include a packing material or filler such as gauze, for example, positioned between film 50 and member 19.

As shown in Fig. 5, member 19 of bandage 10 has a smooth wound contacting surface 24. Wound contacting surface 24 may also be textured or roughened and/or may include a rib, protrusion, channel, or spacer design. By providing member 19 with a rib, protrusion, channel, or spacer, a space is created between surface 24 of layer 20 and wound surface 13. Through holes 46 communicate with this space to permit vacuum source 14 to establish a generally uniformly distributed vacuum or negative pressure to the wound surface 13 and to overhanging tissue 17 to draw blood from the body to the wound surface 13 and to overhanging tissue 17 and to draw exudate from the wound 12 through holes 46 and openings 62, 64, into channels 30, 31 and passageways 42, and out port 40 of cover 22.

The vacuum or negative pressure, which draws blood from the body to the wound surface 13 and draws exudate from the wound 12 up through member 19, promotes the healing of wound 12. The negative pressure is distributed to a bottom portion of wound 12 through holes 46 and is distributed to undermined areas 15 and overhanging tissue 17 of the wound 12 through openings 62, 64 to draw exudate from these areas of the wound 12 through passageways 42 and out port 40 of member 19. As wound 12 heals, granulations form along the wound surface 13. Granulations, therefore, are the replacement within the wound bed of tissue lost. As the

granulations fill in the wound bed causing the wound 16 to heal, member 19 rides up on the wound surface 13 on top of the granulations which are formed.

As mentioned above, port 40 of cover 22 communicates with vacuum source 14 and/or irrigation source 16 via connecter 23 and tube 41. As shown in Fig. 1, a switch valve 55 is provided which allows the caretaker to switch between the use of the vacuum source 14 and the irrigation source 16. It will be appreciated that a mechanism other than the switch valve 55 maybe used selectively to couple the vacuum source 14 or the irrigation source 16 to the bandage 10. Simple tube clamps, for example, may be used selectively to open and close the tube set provided with bandage 10. When valve 55 is switched to operate the vacuum source 14, the vacuum suction draws exudate up through holes 46 and openings 62, 64, radially inwardly through passageways 42 toward port 40, and finally through connecter 23 and tube 41. Although tube 41 has been referred to as vacuum tube 41, tube 41 may also be used as an irrigation tube carrying liquid to the wound 12 from irrigation source 16, as described above.

Although this invention has been described in detail with reference to certain embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.